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December 18, 2003

CERTIFICATE OF MAILING 37 C.F.R 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS DD, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-

1450, on the date below: December 18, 2003

Date

Robert E. Hanson

MS DD

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

RE:

U.S. Patent Application No. 10/620,049 entitled "ANTIBODIES WITH INCREASED AFFINITIES FOR ANTHRAX ANTIGENS" - Barrett R. Harvey et al.

Our reference: UTSB:721US

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references A1-A2, B1, and C1-C29.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSB:721US.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,

Robert E. Hanson

Reg. No. 42,628

REH/kmv

Encl.: as noted

25367590.1

OIP # 1000 E

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of:

Barrett R. Harvey et al.

Serial No.: 10/620,049

Filed: July 15, 2003

For: ANTIBODIES WITH INCREASED

AFFINITIES FOR ANTHRAX ANTIGENS

Group Art Unit: 1653

Examiner: Unknown

Atty. Dkt. No.: UTSB:721US

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Robert E. Hanson

#### **INFORMATION DISCLOSURE STATEMENT**

MS DD

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as

defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first

Official Action reflecting an examination on the merits, and hence is believed to be timely filed

in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the

filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R.

§§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the

Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit

Account No.: 50-1212/UTSB:721US.

Applicants respectfully request that the listed documents be made of record in the present

case.

Respectfully submitted,

Robert E. Hanson

Reg. No. 42,628 Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, Texas 78701 (512) 474-5201

Date:

December 18, 2003

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Form PTO-1449 (modified)	A	tty. Docket No.	Serial No.	
	U	TSB:721US	10/620,049	
List of Patents and Publications for	Applicant's A	pplicant		
	B	arrett R. Harvey <i>et a</i>	<i>I</i> .	
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U.S. Patent Documents Foreign I		nt Documents	Other Art	

#### **U.S. Patent Documents**

See Page 1

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,601,823 A	2/11/1997	Williams et al.	424	167.1	12/02/93
	A2	6,329,156 B1	12/11/01	Cirino et al.	435	7.21	03/22/99

## **Foreign Patent Documents**

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	В1	WO 99/36569	01/20/99	PCT		-	

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Bradley et al., Nature, "Identification of the cellular receptor for anthrax toxin," 8;414(6860):225-229, 2001.
	C2	Bull and Parrich, "A binding contract for anthrax," Science, 297:201-202, 202.
	C3	Chen and Okayama, "High-efficiency transformation of mammalian cells by plasmid DNA," Mol. Cell Biol., 7(8):2745-2752, 1987.
	C4	Chen et al., "Isolation of high-affinity ligand-binding proteins by periplasmic expression with cyto metric screening," Nat. Biotechnol., 19:537-542, 2001.
	C5	Chen et al., "In vitro scanning saturation mutagenesis of all the specificity determining residues in an antibody binding site," <i>Protein Eng.</i> , 12:349-356, 1999.
	C6	Daughterty et al., "Quantitative analysis of the effect of the mutation frequency on the affinity maturation of antibodies," Proc. Natl. Acad. Sci., USA, 97:2029-2034, 2000.
	C7	Ezzell et al., "Immunoelectrophoretic analysis, toxicity, and kinetics of in vitro production of the protective antigen and lethal factor components of Bacillus anthracis toxin," <i>Infect. Immun.</i> , 45:761-777, 1984.
	C8	Georgiou et al., "Display of heterologous proteins on the surface of microorganisms: from the screening of combinatorial libraries to live recombinant vaccines," Nat. Biotechnol., 15:29-34, 1997.

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See Page 1

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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Form PTO-1449 (modified)		Atty. Docket No. UTSB:721US	Serial No. 10/620,049	
List of Patents and Publications for INFORMATION DISCLOSURE ST	••	Applicant Barrett R. Harvey <i>et al</i> .		
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	C9 _	Hayhurst and Georgiou,. "High throughput isolation," Curr. Opin. Chem. Biol., 5:683-689, 2001.
	C10	Hayhurst and Harris, "Escherichia coli Skp chaperone coexpression improves solubility and phage display of single-chain antibody fragments," <i>Protein Expr. Purif.</i> , 15:336-343, 1999.
	C11	Hayhurst et al., "Isolation and expression of recombinant antibody fragments to the biological warfare pathogen Brucella melitensis," J. Immunol. Methods, 276:185-196, 2003.
	C12	Hayhurst, "mproved expression characteristics of single-chain Fv fragments when fused downstream of the Escherichia coli maltose-binding protein or upstream of a single immunoglobulin-constant domain," <i>Protein Expr. Purif.</i> , 18:1-10, 2000.
	C13	Hoess, "Protein design and phage display," Chem. Rev., 101:3205-3218, 2001
	C14	Ivins et al., "Influence of body weight on response of Fischer 344 rats to anthrax lethal toxin," Applies and Environmental Microbiology, 55:2098-2100, 1989.
	C15	Keller and Stiehm, "Passive immunity in prevention and treatment of infectious diseases," Clin. Microbiol. Reviews, 13:602-614, 2000.
	C16	Krebber et al., "Reliable cloning of functional antibody variable domains from hybridomas and spleen cell repertoires employing a reengineered phage display system," J. Immunol. Methods, 201:35-55, 1997.
	C17	Leppla, "Anthrax toxin," Chapter 19 In: Handbook of Experimental Pharmacology, 145:445-472, 2000.
	C18	Li et al., "X-ray snapshots of the maturation of an antibody response to a protein antigen," Nat. Struct. Biol., 10(6):482-488, 2003.
	C19	Little et al., "Characterization of lethal factor binding and cell receptor binding domains of protective antigen of Bacillus antracis using monoclonal antibodies," Microbiology, 142:707-715, 1996.
	C20	Little et al., "Passive protection by polyclonal antibodies against Bacillus antracis infection in guinea pigs," Infection and Immunity, 65:5171-5175, 1997.
	C21	Little et al., "Production and characterization of monoclonal antibodies to the protective antigen component of Bacillus anthracis toxin," Infect. Immun., 56:1807-1813, 1988.

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			Barrett R. Harvey et a	ıL.	
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		July 15, 2003	1653		
3	U.S. Patent Documents	Foreign l	Patent Documents	Other Art	
ر4	See Page 1	See Page 1		See Page 1	

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	C22	Maynard et al., "Protection against anthrax toxin by recombinant antibody fragments correlates with antigen affinity," Nat. Biotechnol., 20:597-601, 2002.
	C23	Mourez et al., "Designing a polyvalent inhibitor of anthrax toxin," Nature Biotechnology, 19:958-961, 2001.
	C24	Pitt et al., "In vitro correlate of immunity in a rabbit model of inhalational anthrax," Vaccine, 19:4768-4773, 2001.
	C25	Sellman et al., "Dominant-negative mutants of a toxin subunit: an approach to therapy of anthrax," Science, 292:695-697, 2001.
	C26	Singh et al., "A dominant negative mutant of Bacillus antracis protective antigen inhibits anthrax toxin in vivo," J. of Biol. Chem., 276:22090-22094, 2001.
	C27	Turnbill et al., "Antibodies to Anthrax Toxin in Humans and Guinea Pigs and Their Relevance to Protective Immunity," Abstract, Med. Microbiol. Immunol., 177:293-303, 1988.
	C28	U.S. Patent Application Serial Number 10/288,269, filed November 5, 2002 (UTSB:720US).
	C29	Wittrup, "The single cell as a microplate well," Nat. Biotechnol., 18:1039-1040, 2000.

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